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09/544,934	04/07/2000	Henrik Stender	35853.1	2473
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FREDMAN, JEFFREY NORMAN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1655

DATE MAILED: 01/18/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/544,934	Applicant(s) Stender et al
Examiner Jeffrey Fredman	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Dec 21, 2001

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-24, 35, and 36 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-24, 35, and 36 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Prosecution Application*

1. The request filed on December 21, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/544,934 is acceptable and a CPA has been established. An action on the CPA follows.

### *Sequence Rules*

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons of record. Applicant is requested to comply with the sequence rules and the September 22, 2000 Notice to comply.

### *Priority*

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Art Unit: 1655

***Claim Rejections - 35 USC § 112***

4. Claims 1-24, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase "probe being capable of hybridising" in claims 1-4. The phrase "capable of" renders the claims indefinite because the capacity of a probe to perform some function is merely a latent characteristic of the probe and this language carries no patentable weight. See MPEP § 2173.05(b).

Regarding claims 3, 4 and later claims, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-24, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Stender et al (WO98/15648).

Stender teaches the identical subject matter in claims 1-24, 35 and 36 of the PCT. Stender can be removed as a reference by properly claiming priority.

Art Unit: 1655

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-24, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over one of Shah et al (U.S. Patent 5, 521,300) or Hogan et al (U.S. Patent 5,541,308) or Britschgi et al (U.S. Patent 5,726,021), any one of the previous in view of Hyldig-Nielsen et al (WO 95/32305).

Shah teaches probe for detecting a mycobacterial target sequence which probes comprise SEQ ID NO: 8 (see column 93, SEQ ID NO: 72) and SEQ ID NO: 85 (see column 77, SEQ ID NO: 35)

Art Unit: 1655

Hogan teaches probe for detecting a mycobacterial target sequence which probes comprise SEQ ID NO: 25 (see column 24, line 21) and SEQ ID NO: 34 (see column 18, line 20).

Britschgi teaches probe for detecting a mycobacterial target sequence which probes comprise SEQ ID NO: 123 (see column 71, SEQ ID NO: 83).

Neither Shah, Hogan or Britschgi teach the use of PNA backbones in oligonucleotide probes.

Hyldig-Nielsen teaches the use of PNA backbones, including a backbone of the formula of claims 6, 15 and 18 (see page 17 of Hyldig-Nielsen) in probes for the detection of microorganisms using 16S rRNA base compositions (abstract). Hyldig-Nielsen expressly teaches that Z is NH, R2 is H, R3 is H, R4 is H, X and Y are O and Q is a nucleobase on page 17. Hyldig-Nielsen further teaches the use of labels and solid phase hybridization systems (page 3 and page 17). Hyldig-Nielsen further teaches the use of kits, which incorporate solid phase capture systems (page 45).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the PNA backbone of Hyldig-Nielsen in the probes of Shah, Hogan or Britschgi since Hyldig-Nielsen teaches that

"The present PNA probes form complexes with complementary nucleic acids which complexes are considerably more stable (higher Tm value) than would be a similar hybrid formed by a typically used nucleic acid probe of corresponding sequence allowing sensitive assays to be made with shorter probes than is the case of typical nucleic acid probes used today. Hybridization with traditionally used nucleic acid probes is much faster in solution than in solid phase hybridization. Due to the high affinity of PNA for nucleic acid, even solid phase hybridization between PNA probes and nucleic acid can be performed rapidly allowing greater flexibility in assay

Art Unit: 1655

format. Hybridization efficiency is only slightly influenced by pH and salt concentration in the hybridization solution allowing PNAs to hybridize under conditions not favourable for ordinary DNA probes. Furthermore, PNAs have a higher thermal instability of mismatching bases whereby PNAs exhibit a greater specificity for their complementary nucleic acids than traditionally used nucleic acid probes of corresponding sequence would do (ref omitted). The structure of PNA is not degraded by nucleases or proteases making the PNA molecule very stable in biological solutions (page 3, line 21 to page 4, line 7)".

An ordinary practitioner would have been abundantly motivated to utilize the PNA backbone in the mycobacterial probes of Shah, Hogan or Britschgi in order to gain the advantages of improved stability, increased specificity, increased speed of hybridization, increased assay format flexibility, and improved resistance to nucleases.

***Allowable Subject Matter***

9. Claims drawn to PNAs comprising SEQ ID Nos: 40, 44, 76, 89 and 90 would be novel and unobvious over the cited prior art. Of course, the claims would be rewritten to overcome the 112, second paragraph rejections.

***Conclusion***

10. This is a CPA of applicant's earlier Application No. 09/544,934. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1655

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the morning are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note

Application/Control Number: 09/544,934

Page 8

Art Unit: 1655

that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

  
**Jeffrey Fredman**  
**Primary Patent Examiner**  
**Art Unit 1655**

January 17, 2002